

K043515

510(k) Summary

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Company: VesCare, Inc.  
28 Cook Street  
Billerica, MA 01821  
Tel: 978 663 2475  
Fax: 978 663 4364

MAR 31 2005

510(k) Number: K043515

Common/Usual Name: Distention and irrigation syringe

Classification: Class I

Description: The device is comprised of 10 biocompatible components including a syringe, a syringe stopper, a ball, stainless steel pin, spring and rod, a green acetal ring, a black acetal pusher, a white acetal knob and body. The device is packaged in a Tyvek blister peel pouch.

The device is used for the preparation and irrigation of venous vessels prior to use as a bypass graft. The device has three settings, which allow the user to limit the nominal pressure up to 150 mmHg, 250 mmHg or 350 mmHg.

Material:

- The syringe barrel and tip shield are made of polypropylene, the syringe stopper is made of polyisoprene, the syringe lubricant is silicone - 60mL Becton Dickson Disposable Single-Use Syringe per ISO 7886-1, ISO 7886-2 and ISO 594-1&2.
- the ball is made of nitrile synthetic rubber (butadiene and acrylonitrile) per ASTM D1418, ISO 1629 Designations: NBR.
- the spring, pin and rod are made from stainless steel per ASTM F899.
- the setting knob, ring, body and pusher are made from colored acetal per ASTM F1855.

Indications: The device is indicated for use in the distention and irrigation of venous vessels prior to use as a bypass graft.

Performance Data: In a review article by Bonchek, LI, in "Prevention of endothelial damage during the preparation of saphenous veins for bypass grafting", J Thorac Cardiovasc Surg 79:911-915, 1980, the author states that because of the potential late consequences of early endothelial damage to vein grafts, distention of veins before grafting to overcome spasm and to identify leaks must be done at controlled pressures.

In a review article by Okon et al, in "Effect of Moderate Pressure Distention on the Human Saphenous Vein Vasomotor Function" Ann Thorac Surg 2004;77:108-15, the authors state that the distention of the human saphenous vein at moderate pressure combined with the application of the effective combination of vasodilative drugs before grafting into the arterial circulation could be a beneficial alternative to the current practice of uncontrolled pressure distention.

Substantial Equivalence: This device is substantially equivalent to the DMC Saphenous Vein Distention System by DMC medical limited per K000704 cleared on May 19, 2000.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

MAR 3 1 2005

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Mr. David Walsh  
Director, Quality Assurance & Regulatory Affairs  
VesCare, Inc.  
28 Cook Street  
Billerica, Massachusetts 01821

Re: K043515

Trade/Device Name: Distention and Irrigation Syringe  
Regulation Number: 21 CFR 878.4200  
Regulation Name: Introduction/drainage catheter and accessories  
Regulatory Class: I  
Product Code: GBX  
Dated: February 17, 2005  
Received: February 28, 2005

Dear Mr. Walsh:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

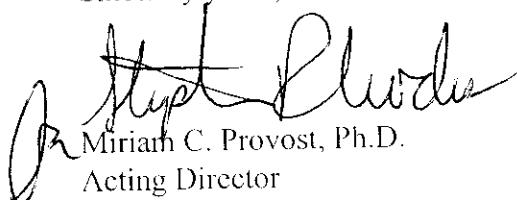
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,



Miriam C. Provost, Ph.D.

Acting Director  
Division of General, Restorative  
and Neurological Devices  
Office of Device Evaluation  
Center for Devices and Radiological Health

Enclosure

VesCare, Inc.  
28 Cook Street  
Billerica, MA 01821  
Tel: 978 663 2475  
Fax: 978 663 4364

**510(k) Number: K043515**

**Device Name:** Distention and Irrigation Syringe

**Indications for Use:**

The device is indicated for use in the distention and irrigation of venous vessels prior to use as a bypass graft.

Prescription Use X  
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use \_\_\_\_\_  
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Steve Gwaltys  
(Division Sign-Off)

**Division of General, Restorative,  
and Neurological Devices**

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